

**K103230 AP-3000 BLOOD GLUCOSE MONITORING SYSTEM,
MAJOR GLUCOSE CONTROL SOLUTION**Apr 24, 2012
540 days to decisionK103230 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k103230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Nov 1, 2010
Decision date	Apr 24, 2012
Days to decision	540 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bestgen Biotech Corp.
Location	Hsin Chu City, TW
Contact	STEVEN SHEN
510(k) history	6 submissions · 6 cleared · 2008-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103230/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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